SUNMARK HEARTBURN RELIEF ACID REDUCER- cimetidine tablet, film coated Strategic Sourcing Services LLC

McKesson Heartburn Relief Drug Facts

Active ingredient (in each tablet)

Cimetidine 200 mg

Purpose

Acid reducer

Uses

- **relieves** heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages

Warnings

Allergy alert: Do not use if you are allergic to cimetidine or other acid reducers

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Ask a doctor before use if you have

- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness**, **sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- kidney disease
- liver disease

Ask a doctor or pharmacist before use if you are

taking

• a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if

- you need to take this product for more than 14 days
- stomach pain continues
- your heartburn continues or worsens

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- adults and children 12 years and over:
- to **relieve** symptoms, swallow 1 tablet with a glass of water
- to **prevent** symptoms, swallow 1 tablet with a glass of water **right before or any time up to 30 minutes before** eating food or drinking beverages that cause heartburn
- do not take more than 2 tablets in 24 hours
- children under 12 years: ask a doctor

Other information

• store at 20°-25°C (68°-77°F)

Inactive ingredients

hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, sodium lauryl sulfate, sodium starch glycolate, titanium dioxide

Questions or comments?

1-800-719-9260

Consumer Information

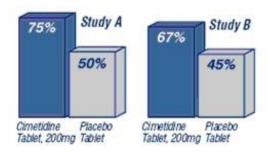
Cimetidine Tablets, 200 mg

Acid Reducer

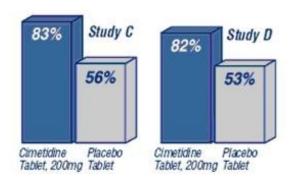
For Heartburn

In clinical studies, Cimetidine Tablets, 200 mg was significantly better than placebo tablets in relieving and preventing heartburn symptoms.

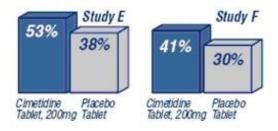
Percent of Heartburn Episodes Relieved



Percent of Patients with Prevention or Reduction of Heartburn Symptoms When Taken 30 Minutes Before a Meal



Percent of Patients with Prevention or Reduction of Heartburn Symptoms When Taken at Time of Meal



Drug Interaction Warnings:

Cimetidine Tablets, 200 mg affects some prescription medicines causing slightly higher levels of those medicines in the blood. Higher blood levels could lead to side effects in rare situations. If you currently take Theophylline (oral asthma medicine), Warfarin (blood thinning medicine) or Phenytoin (seizure medicine), consult your doctor before taking this product.

Brand names of some medicines which contain one of these ingredients include:

THEOPHYLLINE	THEO-DUR® Theochron® Slo-Bid® Uniphyl® Theo-24®		
WARFARIN	Coumadin®		
PHENYTOIN	Dilantin®		

There may be other medicines that contain one of these ingredients. If in doubt about this or about possible effects of Cimetidine Tablets, 200 mg on any other medicines you are taking, talk to your doctor or pharmacist.

Tips for Managing Heartburn

- Do not lie flat or bend over soon after eating
- Do not eat late at night, or just before bedtime
- Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty, and fried foods, chocolate, caffeine, alcohol, even some fruits and vegetables
- Eat slowly and do not eat big meals
- If you are overweight, lose weight
- If you smoke, quit smoking
- Raise the head of your bed
- Wear loose fitting clothing around your stomach

Read the directions and warnings before taking this medication.

Questions or Comments?

1-800-719-9260

Distributed By

Perrigo®

Allegan, MI 49010

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Principal Display Panel

COMPARE TO TAGAMET® HB 200 ACTIVE INGREDIENT

heartburn relief cimetidine tablets USP, 200 mg

Acid Reducer

Just one tablet relieves and prevents heartburn and acid indigestion

TAKE ANY TIME YOU NEED IT:

Before Meal

During Meal

After Meal

Actual Size

ONE TABLET DOSE

Read and retain the important information and drug interaction warnings printed on the product information sheet

30 TABLETS (30 DOSES)



SUNMARK HEARTBURN RELIEF ACID REDUCER

cimetidine tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-246	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CIMETIDINE (UNII: 80061L1WGD) (CIMETIDINE - UNII:80061L1WGD)	CIMETIDINE	200 mg	

Inactive Ingredients			
Ingredient Name	Strength		
HYPROMELLOSES (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)			
POLYSORBATE 80 (UNII: 6OZP39ZG8H)			
PO VIDO NE (UNII: FZ989 GH94E)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			

TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)

Product Characteristics			
Color	WHITE	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	L022
Contains			

ı	Packaging					
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
l	1 NDC:49348-246-44	1 in 1 CARTON	09/19/2003			
ı	1	30 in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075285	09/19/2003	

Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 11/2019 Strategic Sourcing Services LLC